REMARKS

Claims 1 -7 are pending in the application. Claim 1 is amended. Applicants reserve the right to pursue any withdrawn or canceled subject matter in one or more continuation or divisional applications.

Rejections under 35 U.S.C. §112

The Examiner has rejected claims 1-7 under 35 U.S.C. §112 second paragraph as indefinite because it is allegedly unclear to whom the compound is being administered. The claims have been amended to recite that the compound is administered to "a human patient in need thereof" to overcome this rejection.

The Examiner has also rejected claims 1-7 for the recitation of the phrase "optionally substituted." It would be clear to one skilled in the art that the residue of the amino acid, as described in the specification on page 7, lines 1-6, could be optionally substituted.

The Examiner has also rejected claims 1-7 stating that it is not clear whether Ala, Val, Leu or Ile represents a substitution on another amino acid or a different substitution for R1. The claims have been amended to clarify that residue R1 is, alternatively, a residue of the amino acids.

Prior Art Rejections under 35 U.S.C. §§ 102 and 103

The Examiner has rejected claims 1-7 under 35 U.S.C. §102(b) and under 35 U.S.C. §103(a) over Vandai (U.S. 5,212,158).

The '158 patent discloses compounds falling under formula (I) of present claim 1 and describes the use of these compounds for the treatment of amnesia. There is also a general statement that, based on their nootropic effects, these compounds can be used for other diseases including Alzheimer's disease (column 4, line 10). However, there is no specific teaching in the

reference of the compounds recited in the amended claims used to treat neurodegenerative diseases. Indeed, the '158 patent was not enabled for the treatment of Alzheimer's disease as there was no way to use the compound for the method of treatment at the time of its filing, and the statements made therein are clearly merely speculative.

At the time of the filing of the '158 patent, there was no clear way that anyone skilled in the art could use any of the compounds described in the patent in treatment of Alzheimer's disease. In 1987, the priority year of the reference, Alzheimer's disease was ascertained post-mortem and there was no diagnostic test available. Therefore, it would have been difficult to treat the disease with the compound, as it was difficult to even identify an Alzheimer's patient until after they had died. Furthermore, the '158 patent does not provide any support that the anti-amnesic effect of nootropic substances, such as that described in the '158 patent, had any therapeutic effect on the treatment of neurodegenerative diseases. Lastly, any skilled artisan would not know which of the compounds described in the reference could potentially be useful for the treatment of Alzheimer's, and it would therefore have taken undue experimentation, indeed experimentation that would have been difficult at the time of the '158 filing, to reach the method recited in the amended claims. Therefore, although the '158 patent discloses substances that overlap with those recited in the amended claims, the reference does not disclose or suggest embodiments of the amended claims, which recite "[a] method for the treatment of neurodegenerative diseases comprising administering an effective amount of a compound of formula (I) to a human patient in need thereof."

The claims are not obvious in view of the '158 patent. The Examiner apparently relies on the disclosure of the anti-amnesic properties of the compounds to support the contention that it would have been obvious to use the compounds and methods taught by Vandai in the treatment of neurodegenerative diseases. Contrary to the Examiner's assertion, amnesia is not a neurodegenerative disease. Amnesia is not even a specific disease, but instead is a *symptom* that may potentially have its origin both in neurodegenerative diseases such as Alzheimer's disease or can be induced, for example, by administering drugs such as scopolamine, diazepam or barbital.

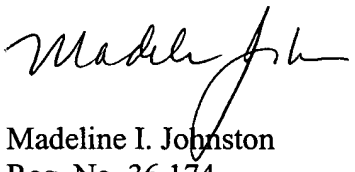
Double Patenting

The Examiner has provisionally rejected claims 1-7 under the judicially created doctrine of obviousness-type double patenting over claims 1-7 of copending Application no. 10/635,808. The Examiner has apparently equated the treatment of neurodegenerative diseases disclosed in the pending application with the treatment of postlesional diseases disclosed in the '808 application.

Contrary to the Examiner's assertion, these claims do not cover overlapping subject matter. A postlesional disease of toxic origin, as recited in the '808 application, is *not* the same a neurodegenerative disease and *does not* encompass Alzheimer's disease. A postlesional disease of toxic origin is induced by exogenous toxins such as alcohol, drugs, heavy metals, etc. In support of this, Alzheimer's disease and postlesional diseases of toxic origin are differently classified by the World Health Organization. Alzheimer's is classified in block 30 of the International Statistical Classification of Diseases and Related Health Problems (see www.who..int/whosis/icd10/) while postlesional diseases of toxic origin (i.e. intoxication) are classified as 'injury' in block S. A skilled person therefore can clearly distinguish Alzheimer's disease form a postlesional diseases of toxic origin.

Applicants believe no further fees are due with this response, however if the Examiner determines that any fees are due, the Commissioner is hereby authorized to charge any additional fees associated with this response to Deposit Account No. 11-0980.

Respectfully submitted,



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